K113608

Section 5
510(k) Summary

APR 10 2012

(1) Submitter:

NUXEN S.R.L..
1053 Ayacucho, 3rd A (C1111AAE)
Ciudad Autónoma de Buenos Aires, Argentina
Tel +54 11 4241 7762

Contact person: Pablo Lagostena

Preparation Date: August 1, 2011

(2) Device Proprietary Information

Trade Name:	DEFLEX
Common Name:	Polymer for Injection of Denture Bases
Classification Name:	Denture relining, repairing, or rebasing resin (21 CFR 872.3760, Product Code EBI)

(3) Predicate Devices

510(k) Number	Trade Name	Manufacturer
K053060	TCS unbreakable	Thermoplastic Comfort Systems, Inc.

(4) Device Description

Deflex is a pigmented granulated polyamide resin that belongs to the group of amorphous polyamides or co polyamides, which is used for the manufacturing of partial, complete and combined dentures.
The product is presented in pellets, packed in an aluminum canister (as a primary packaging), and then in a vacuum sealed aluminized plastic bag (as a secondary packaging).

The polyamide granules are pigmented so as to achieve aesthetic effects on the manufactured denture.

(5) Intended Use

This product is indicated for the manufacturing of bases of partial or full removable dentures, occlusal splints and night guards through heating and pneumatic injection of the material, following the Instructions of Use that come with the product.

(6) Comparison to predicate device

Deflex resin and TCS resin have been compared in terms of:

- Intended use
- Indications of use
- Flexural strength
- Characterization

Finding that:

- Both products have the same intended use
- Both products have similar indications of use
- Both products have a flexible and resilient behavior being DEFLEX more resistant than its predicate
- Both materials belong to the polyamide family

Arriving to the conclusion that Deflex Resin Material is at least as safe and effective as its predicate device

(7) Non Clinical Testing

The following tests have been carried out in order to demonstrate product's safety and effectiveness

TEST	Standard or Test Method applied
Material characterization	Internal laboratory method
Mechanical properties	EN 20795-1:2009 *
Swelling	EN ISO 10993-13:2009

Identification and quantification of degradation products	EN ISO 10993-13:2009
In Vitro cytotoxicity (Direct Contact Test)	EN ISO 10993-5:2009
In Vitro cytotoxicity (Agar diffusion test)	EN ISO 7405:2008
In Vitro cytotoxicity (Filter diffusion test)	EN ISO 7405:2008
Intra cutaneous reactivity	EN ISO 10993-10:2010
Delayed hyper sensitivity	EN ISO 10993-10:2010
Sub acute systemic toxicity test	EN ISO 10993-11:2009
Genotoxicity(Ames Test)	EN ISO 10993-3:2009

* equivalent to test method described in ANSI+ADA+12-2002+(R2008)

(8) Clinical Investigation

Clinical investigation is not required for this device in order to demonstrate its safety and effectiveness.

(9) Conclusion

NUXEN S.R.L. concludes that the DEFLEX Resin for dental prostheses is substantially equivalent to its predicate device. Based upon test data submitted, the product included in this submission can be safely and effectively used for manufacturing bases of partial removable or complete dentures through heating processes and pneumatic injection of the material, according to the technique indicated in the "Use Indications" that come with the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NUXEN S.R.L.
C/O Mr. Hernan Ilari
IC Ingenieria
9741 Juan B Justo
Buenos Aires
ARGENTINA C1408ALB

APR 16 2012

Re: K113608
Trade/Device Name: DEFLEX
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: April 2, 2012
Received: April 2, 2012

Dear Mr. Ilari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113608

Device Name:

DEFLEX

Indications for Use:

This product is indicated for the manufacturing of bases of partial or full removable dentures, occlusal splints and night guards through heating and pneumatic injection of the material, following the Instructions of Use that come with the product.

Prescription Use ____X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Shenalonen for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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